

Paper Abstract
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ANSI 13.30 AND THE LAW OF UNINTENDED CONSEQUENCES
Subtitle: "To Three or not to Three, that is the question"

While ANSI N13.30 standard, "Performance Criteria for Bioassay," was nearly twenty years in the making, it still does not adequately deal with cases where the analyst is faced with trying to determine a zero answer in the face of positive background and blanks. Statistical models depend on reasonable samplings of large populations such that sampling errors are low. For the most part radiological samplings are not subject to large sampling errors. However, as the best available technology eats further and further into improving detection limits we have found ourselves, particularly in *in vitro* bioassay, moving from the doable to the impractical to the nearly impossible. In zero level analysis there are instances where only a few counts change over the period of several thousand minutes of counting can considerably change the answer. These instances of zero or near zero results and a proposal on how to deal with background and blank in these cases are presented and discussed. The impact and/or advisability of the use of the added "three" to the prescribed minimum detectable amount formula is also discussed. The question of whether, in an attempt to please the modelers and regulators, we have left science in the dust, is raised, if not resolved.